K102556

Section 5

OCT - 7 2010

510(k) Summary
Prepared September 30, 2010

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Submission Date: September 1, 2010

Device Name: Volpara Imaging Software

Common Name: Imaging Software

Classification:
Regulatory Class: II
Review Category: Class II
Classification Panel: Radiology
System, Imaging Processing; 21 CFR 892.2050; LLZ

A. Legally Marketed Predicate Devices
The modified software is substantially equivalent to the Quantra software cleared pursuant to K082483.

B. Device Description:
Volpara™ analyzes raw ("for processing") digital mammograms in a fully automated, volumetric fashion and produces a quantitative assessment of breast composition, namely volume of fibroglandular tissue in cubic centimeters (cm^3) volume of breast tissue in cm^3 and their ratio, volumetric breast density. Volpara v1.3 handles DICOM files as input

Volpara v1.3has been built and tested on Windows XP and Linux

Volpara software is a component which accepts as input digital mammography images along with associated calibration data. The software processes the image according to proprietary algorithms. It provides measures of:

- volume of fibroglandular tissue
- volume of breast
- breast density

The software does not perform image display but outputs to the console.

C. Intended Use

Volpara is a software application intended for use with digital mammography systems. Volpara calculates volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Volpara provides these numerical values for each image to aid radiologists in the assessment of breast tissue composition. Volpara produces adjunctive information. It is not an interpretive or diagnostic aid. Volpara is a software application which runs on Windows or Linux-based computers.

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate, Hologic Quantra software with regard to both intended use and technological characteristics. The dev ices have substantially equivalent indications for use and technological characteristics. Both devices are labeled as providing adjunctive information which is not an interpretive or diagnostic aid.

Table 1 Substantial Equivalence Comparison Table

	Predicate Device Quantra K082483	Submission Device Volpara
Intended Use	Quantra software application intended for use with Hologic digital mammography systems. Quantra calculates volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Quantra provides these numerical values for each breast to aid radiologists in the assessment of breast tissue composition. Quantra produces adjunctive information. It is not an interpretive or diagnostic aid. Quantra is a software application which runs on Hologic Cenova DICOM server.	Volpara is a software application intended for use with digital mammography systems. Volpara calculates volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Volpara provides these numerical values for each image to aid radiologists in the assessment of breast tissue composition. Volpara produces adjunctive information. It is not an interpretive or diagnostic aid. Volpara is a software application which runs on Windows or Linux-based computers
Intended Users	Radiologists	Radiologists
Image Source	Digital mammography images	Digital mammography images
Compatibility	Hologic Digital Mammography System	GE and Hologic Digital Mammography Systems
Anatomical Area	Breast	Breast
Assessment scope	Average of images for each breast	Provides results per image
Assessment type	Volumetric	Volumetric
Operating environment	Not specified in product labeling	Windows or Linux-based computers
Image storage and report generation	Yes appears to generate a DICOM structured report to send to PACS	Yes output to the console

Classification	90LLZ 892.2050	90LLZ 892.2050
Software Level of Concern	Minor	Moderate

E. Performance Data

The Volpara software has been verified and validated according to the company's design control process. All of the documents specified in FDA's software guidance document have been submitted in the 510(k) Notification. A risk analysis compliant with ISO 14971 has been completed and incorporated into the development effort. Software testing included both unit level and integrated system level testing. A report of outstanding anomalies was included in the software information. Verification and Validation testing utilized images acquired from detectors manufactured by both GE and Hologic.

Verification Bench testing of Volpara volumetric breast density software included:

- Measurements of Volpara as compared to known values of standardized and calibrated breast phantoms
- Volpara was run over x-ray images for which a BI-RADS score was available from a MQSA qualified radiologist followed by a comparison of the two sets of data
- Volpara was run over x-ray images of breasts for which there was 3D breast MRI data with a comparison of estimates of fibroglandualar tissue
- Volpara was run over substantial datasets where we have the women's age and results compared with the expected and known decrease in breast density with age
- Volpara was run over substantial data sets and the results for left and right breasts and CC and MLO views were compared to confirm that the results were the similar for each view and each breast.
- Volpara was run over substantial data sets where the same woman had been imaged on GE and Hologic systems one year apart and the results were compared to confirm they were similar.

Clinical Validation testing of Volpara volumetric breast density software included :

- Beta site testing to assess the ability of physicians to successfully integrate the software into their existing systems as well as assess usability for target users
- Beta site testing to collect minimum, average and maximum Volpara breast densities and compare these to other existing databases

All verification and validation testing was successful in that established acceptance criteria was met for all of the tests conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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OCT - 7 2010

Re: K102556
Trade/Device Name: Volpara Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 1, 2010
Received: September 7, 2010

Dear Dr. Pickering:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K102556

OCT - 7 2010

Device Name: Volpara Imaging Software

Indications for Use:

Volpara is a software application intended for use with digital mammography systems. Volpara calculates volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates. Volpara provides these numerical values for each image to aid radiologists in the assessment of breast tissue composition. Volpara produces adjunctive information. It is not an interpretive or diagnostic aid. Volpara is a software application which runs on Windows or Linux-based computers.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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